

## **REMARKS**

### **Application Amendments**

Claim 1 has been amended to define the device of the Applicants' invention as having a flag-like structure. Claim 4 has been amended to correct a typographical error and to more clearly claim the Applicants' invention. Claim 5 has been amended to address the Examiner's rejection under 35 USC §112 and to more clearly claim the Applicants' invention. Claim 14 has been amended to more clearly claim the Applicants' invention. New claims 31 and 32 have been added as dependent claims to now amended claim 1, with claim 31 incorporating elements now deleted from claim 1. Claim 18 has been amended to provide proper claim dependency and to correct a grammatical error. Support for these amendments may be found throughout Applicants' Specification (for example, at paragraphs [0052], [0110]-[0114], [0149] and [0250]) and Figures 5-6. No new matter has been added.

### **Claim Rejection under 35 USC §112, Second paragraph**

Claims 1, 3-6, 9-10 and 13-22 stand rejected by the Examiner under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner asserts that amended claim 1 contains a Markush group of materials used in producing the claimed particles and that many of these appear to be coextensive.

The Examiner asserts that claim 5 sets out both "synthetic" and "genetically engineered proteins".

Thus, the Examiner contends that as such, the metes and bounds of the claims are indefinite.

Applicants have amended claim 1, deleting the Markush group and incorporating it in new claim 31. The terms "resin", "hydroxyapatite", "polylactide poly(L-lactide)", "poly(D-lactidepoly)", and "copolymer derived therefrom polylactide poly(L-lactide) or poly(D-lactidepoly)" have been excluded from new claim 31.

Applicants have rewritten claim 5, deleting the term "a genetically engineered protein polymer".

Accordingly, this rejection of the claims is now obviated.

### **Claim Rejections under 35 USC §102**

Claims 1, 3-5, 9, 10, 21 and 22 stand rejected by the Examiner, for the reasons of record, under 35 U.S.C. §102 (b) as allegedly being anticipated by Buscemi, et al. (US 5,500,013; “Buscemi”).

Applicants respectfully traverse this rejection as applied to the amended claims.

Buscemi discloses a biodegradable stent, for implanting into the vasculature, having a tubular body made of a substantially biodegradable matrix essentially saturated with drugs that are released as the matrix degrades, and comprising a plurality of fibers disposed around the tubular body, and a biodegradable strengthening material in contact with the matrix. Buscemi does not disclose or teach an implantable device having fibers that float or lie in the bloodstream.

Applicants contend that Applicants’ base claim, as amended, is not anticipated by Buscemi. Applicants’ claim 1 is directed to an implantable device comprising a biodegradable matrix material capable of dissolving upon contact with blood, and constructed to degrade gradually until complete degradation as the biodegradable matrix material dissolves. Applicants’ device comprises a ring-shaped holding structure and a plurality of fibers that comprise at least one drug coated onto or incorporated into fiber matrix material; the fibers being attached to the holding structure at one end of each fiber, with their remaining portions freely floating or lying in the bloodstream in a flag-like manner (as illustrated in Applicants’ FIG. 5 and FIG. 6). Applicants contend that although Buscemi discloses a plurality of fibers, those fibers are “disposed around the main body” of the stent, such as encircling the outer surface of the stent in an annular alignment (as illustrated in Buscemi’s Fig. 1). Although Buscemi’s fibers contact the stent body, they are not attached to the stent structure at only one end of each fiber with their remaining (non-attached) portions freely floating or lying in the bloodstream, in a flag-like manner; rather, they appear to contact the stent body along the entire fiber length and effectively form a part of the stent’s outer structure. Applicants’ fibers are not disposed “around” (common definitions for “around” include: in a circle; circularly; in circumference; encircling; so as to encircle, surround, or envelop; on all sides; on every side) the ring-shaped structure, rather, each fiber is attached at only one end to said structure, while the greater portion of each fiber freely floats or lies in the bloodstream to deliver at least one drug. Further, Applicants’ fibers are utilized for the sole purpose of distributing at least one drug in the bloodstream; whereas,

Buscemi's disclosure and figures teach the fibers as being primarily utilized as a structural element that provides strength to the stent to facilitate the opening of an occlusion in the vessel and to withhold the centripetal forces of the vessel wall. Hence, the location of those fibers "around" the tubular stent body, which enables this structural use.

In view of the reasons stated above, Applicants submit that all of the elements of Applicants' amended base claim 1 are not found in Buscemi, as Buscemi fails to disclose or teach a plurality of fibers that are attached at one end to the stent structure and their remaining portions freely floating or lying in the bloodstream, in a flag-like manner. Accordingly, Applicants' claims are not anticipated by Buscemi. It is respectfully submitted that amended base claim 1 and claims depending therefrom, claims 3-5, 9, 10, 21, 22, and new claims 31 and 32, are now in condition for allowance and that the Examiner's rejection should be withdrawn.

## **CONCLUSION**

For all of the foregoing reasons, it is respectfully submitted that amended claims 1, 3-6, 9-10 and 13-22 and new claims 31 and 32 are in condition for final allowance. Notice to such effect is respectfully requested.

This response is being timely filed, with the payment of the requisite fee for the one-month extension requested herewith. No other fees are believed to be due by the present amendments.

Should the Examiner have any questions or requires any additional information from Applicants' attorney, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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